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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,350	11/23/2005	Charles Achkar	CCA-10-PCT-US	5748

7590 01/06/2009

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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/558,350	ACHKAR ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22-27,48 and 49* is/are pending in the application.

4a) Of the above claim(s) *6,7,9,10,13,17,19 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,11,12,14-16,18,22-26,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 08/26/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-5, 8, 11-12, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudas (US 5,786,391, see IDS dated 11/23/05) in view of Lee (US Pregrant Pub 2002/0002162).

Gudas et al teaches the administration of all trans-4-oxo-retinol for the treatment of acute promyelocytic leukemia (col 15 lines 20-60, Example VI).

As Applicants point out in the response dated 08/26/2008, Gudas et al does not suggest the coadministration of a growth factor inhibitor, but instead suggests the addition of a growth factor.

Lee teaches treatment of promyelocytic leukemias (paragraphs 61 and 62) by administrating a combination of drugs, which can include the coadministration of Iressa (paragraph 208).

Lee does not teach the addition of all trans-4-oxo-retinol in the treatment.

While the addition of a growth factor is suggested in the primary reference, it is noted that that is in only one embodiment. Additionally, the secondary reference has a later published date, by almost four years (not counting the priority of the patent filing) and therefore, the teachings of the secondary reference appear to correct the misunderstanding of the primary reference with regards to the addition of the growth factor. At the time of filing, one of ordinary skill in the art, would have recognized the ability to combine the primary treatment with compounds later found to have an effect with the same disorder, such as disclosed in the secondary reference. This position is consistent with well-established precedent holding that it is prima facie obvious to combine compositions known to be individually useful together so as to provide a third

composition for the same use. See, e.g., In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudas (US 5,786,391, see IDS dated 11/23/05) in view of Lee (US Pregrant Pub 2002/0002162), the combination further in view of Achkar (US Pregrant Pub 2001/0049365, see Applicants' IDS dated 11/23/2005).

Gudas and Lee are discussed above, but do not disclose the addition of calcitriol.

Achkar discloses a method of treating patients with leukemia, particularly acute promyelocytic leukemia, with a combination of oral doses of 4-oxo-retinol or 4-hydroxy-retinol and oral doses of calcitriol, where the results are a reduced tumor burden, prolonged remission, and/or permanently cured (Example 6 at paragraph 91).

Achkar does not disclose the coadministration of Iressa when treating leukemia.

Again, one of ordinary skill in the art would have been motivated to have combined the agents of the primary and secondary references with the tertiary reference in order to provide a new chemotherapeutic treatment, useful for the same purpose (treating promyelocytic leukemias). This position is consistent with well-established precedent holding that it is prima facie obvious to combine compositions known to be individually useful together so as to provide a new composition for the same use. See, e.g., In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980).

Claim 18, 48, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratain et al. (Blood, 70 (5) (1987) 1412) in view of the combination of Gudas (US 5,786,391, see IDS dated 11/23/05), Lee (US Pregrant Pub 2002/0002162), and Achkar (US Pregrant Pub 2001/0049365, see Applicants' IDS dated 11/23/2005 cite AB).

Ratain et al teaches treating non-small-cell carcinoma of the lung with the combination of etoposide and cisplatin, where the treatment can trigger leukemias, including acute promyeloctic leukemia (see pg 1415, last paragraph).

Ratain et al does not teach the method of treating acute promyeloctic leukemia as instantly claimed.

Gudas, Lee, and Achkar are discussed above, but do not disclose the addition of cisplatin in the method of treatment.

Because the instant claims do not disclose the timing for the administration of various dosages during the method of treatment, the claims are given the broadest reasonable interpretation, which includes treatment of non-small-cell lung cancer with cisplatin, followed by treatment of acute promyeloctic leukemia resulting triggered by the cisplatin.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612